

# A program of operative angioplasty: Endovascular intervention and the vascular surgeon

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**Purpose:** Vascular surgeons are ideally suited to select and perform endovascular interventions either as primary therapy or as an adjunct to bypass surgery. Attaining proficiency in endovascular techniques is an important goal in the training of vascular surgeons. We report our initial experience with a program of endovascular intervention performed in the operating room by vascular surgeons.

**Methods:** During the previous three years, we performed 109 angioplasty procedures, 60 aortoiliac (55%), 32 femoropopliteal (29%), and 17 popliteal/tibial (16%), using guide-wires and angioplasty balloons directed by intraoperative digital subtraction C-arm arteriography with road-mapping capabilities. Indications for angioplasty included disabling claudication in 59 patients (54%), rest pain in 18 (17%), and tissue loss in 32 (29%). Angioplasty was accompanied by stent placement in 39 of 60 aortoiliac procedures (65%) and in two of 32 femoral procedures (6%). In 16 cases (15%), the endovascular procedure was performed in conjunction with a bypass procedure. In selected cases (15, 14%), duplex scanning was the sole diagnostic method used before surgery to identify the lesion, eliminating the need for preoperative arteriographic scans. Segmental pressure measurements, duplex ultrasound scans, and treadmill exercise testing as indicated were performed before and after surgery. The efficacy of the endovascular intervention was assessed at 3-month intervals during the first year and at 6-month intervals thereafter.

**Results:** A successful result was defined using criteria recommended by the Ad Hoc Subcommittee on Reporting Standards for Endovascular Procedures from the Society for Vascular Surgery/International Society for Cardiovascular Surgery. This included the combination of symptomatic improvement, obtaining an anatomically successful result with <30% residual lumen stenosis, and elimination of the translesion gradient with an improvement in high thigh-brachial index or ankle-brachial index greater than 0.15. Initial success was achieved in 55 of 60 aortoiliac (92%), 28 of 32 femoropopliteal (88%), and 16 of 17 popliteal/tibial (94%) angioplasty procedures. Clinical follow-up has been achieved in all cases, with continued clinical success rates of 80%, 75%, and 82% for aortoiliac, femoropopliteal, and popliteal/tibial angioplasty procedures, respectively, with a mean follow-up of 15.7 months.

**Conclusion:** These results confirm the value of a program in which C-arm technology was used by vascular surgeons in the performance of angioplasty and stenting procedures in the operating room. This experience in therapeutic endovascular intervention will facilitate the credentialing process for future vascular surgeons. (*J Vasc Surg* 1996;24:963-73.)

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Vascular surgeons traditionally have managed patients who have a wide range of vascular disease and they thereby offer superior diagnostic and therapeutic options. This encompasses the selection and performance of endovascular procedures. Our approach has been to establish an interventional program in the operating room, whereas others have addressed the issue by establishing a referral relationship with an interventional radiologist or cardiologist. This collaborative approach, however, has some theoretic limi-

tations. Responsibility to the patient for complications that result from procedures that are performed by others and the issue of preprocedural surgical evaluation and clinical diagnostic follow-up on a procedure performed by a colleague resulted in our decision to pursue a program of operative endovascular intervention for iliac and femoropopliteal occlusive disease.

The task of determining how a vascular surgeon can deliver these services, however, has frustrated the advancement of this portion of our practice and complicated our attempts to add an endovascular component to our training program. Four alternative locations and collaborative approaches exist: using the angiography suite, using the cardiology suite, establishing an independent facility, or using an existing facility such as the operating room. The first and second alternative approaches involve the interdisciplinary use of space, which in many instances is not feasible. The development of the freestanding unit may be the ideal approach, but it probably would be a complex and expensive undertaking in most institutions. The operating suite then represents the preferred option for the development of an endovascular program that is managed by vascular surgeons.

Our objective was to demonstrate the utility of using conventional C-arm imaging techniques, which are available in virtually all operating suites, to establish a surgically based program in endovascular therapeutics. Our goal was to use these techniques as alternatives to standard vascular surgical procedures or as adjuncts to more complex arterial revascularization procedures.

The first author of the report on this series underwent a formal 1-year fellowship in diagnostic and therapeutic angiographic endovascular intervention in addition to a standard 2-year vascular surgical fellowship. The second and third authors had had substantial experience in the development and the evaluation of laser-assisted angioplasty procedures. They have disseminated this experience within the division to our vascular surgical trainees and to our vascular attending surgeons by a policy of planned proctoring. All of the surgeons who perform these procedures have done so only after having met the credentialing criteria that are outlined by the Ad Hoc Committee on Credentialing of the Joint Councils of the vascular surgical societies.<sup>1</sup>

## PATIENTS AND METHODS

Patients were candidates for endovascular intervention if they reported lifestyle-limiting claudication refractory to standard exercise regimens and smoking cessation, or alternatively demonstrated rest pain or

ischemic tissue loss. Either angiographic or duplex ultrasound scans were performed before surgery to identify lesions that were potentially amenable to treatment.

### Patient assessment

**Clinical evaluation.** Stratification of patients on the basis of their symptoms was performed using recommendations outlined by the Ad Hoc Subcommittee on Reporting Standards for Endovascular Procedures.<sup>2</sup> The clinical grades I (claudication), II (rest pain), and III (tissue loss) were determined for all patients.

**Hemodynamic assessment.** Doppler-derived segmental pressure measurements and computed ankle-brachial indexes (ABI) and thigh-brachial indexes (TBI) were obtained in all cases. Postexercise index measurements, pulse-volume recordings, and Doppler scans were performed in selected cases.

**Risk factors.** Patients were classified according to their history of smoking, hypertension, diabetes mellitus, hypercholesterolemia, renal insufficiency with a creatinine level greater than 2.0 mg/dl, chronic obstructive pulmonary disease, or coronary artery disease.

### Description of lesion

**Location.** We classified all lesions by anatomic site, using three groups: aortoiliac (including aorta and common iliac and external iliac arteries), femoropopliteal (including common femoral, deep femoral, superficial femoral, and above-knee popliteal arteries), and popliteal/tibial (including below-knee popliteal, anterior tibial, tibioperoneal trunk, posterior tibial, and peroneal arteries).

**Type.** Using information obtained from a review of preoperative or intraoperative angiographic scans or duplex scans, we characterized lesions according to occlusion versus stenosis, combined with measurements of length and assessment of runoff vessels. The length of the treated lesion was separated into the following categories:  $\leq 2$  cm,  $> 2$  cm to 5 cm,  $> 5$  cm to 10 cm, and  $> 10$  cm. The status of the runoff arteries was graded as either poor (0 to 1) or good (2 to 3). Runoff was defined as an adequately patent artery distal to the treated site ( $< 50\%$  stenosis by angiographic appearance or its equivalent on Duplex scan). The superficial and deep femoral arteries are the runoff vessels for iliac artery lesions, and the tibial arteries are the runoff vessels for procedures performed on femoral or popliteal arteries.

### Criteria for early success

The treatment outcome was based on an intent-to-treat protocol and included all patients who con-

sented to undergo the procedure in the operating room. When more than one procedure was performed on the same arterial segment (i.e., common iliac angioplasty followed by deployment of a stent, and repeat post-stent deployment angioplasty), this was reported as a single endovascular procedure, with efficacy being determined by final outcome of all component procedures.

When the endovascular procedure was performed in conjunction with a surgical reconstruction or with another endovascular procedure of an adjacent inflow or outflow vascular bed, the patency rates of each vascular bed were reported separately. Clinical or hemodynamic failures for either component of therapy in these patients, however, were reported as being failures for both procedures.

The therapeutic results were based on the clinical, hemodynamic, and imaging or anatomic factors. All three criteria must have shown improvement in order for the result to be counted as a success. The definitions for success for each factor are outlined below.

**Clinical success.** Clinical success required symptomatic improvement of the patient as compared with their preprocedural assessment. Claudication was improved if resolved or improved greater than 50%. Rest pain must have been resolved, and tissue loss required healing with limb salvage.

**Hemodynamic improvement.** Hemodynamic improvement was defined as an improvement in the high thigh-brachial index greater than 0.15 for patients undergoing aortoiliac procedures, or improvement in the ankle-brachial index greater than 0.15 for patients undergoing femoropopliteal or popliteal/tibial procedures.

**Anatomic success.** Initial anatomic success was defined as a residual luminal stenosis <30% of normal diameter as measured by an intraoperative digital-subtraction angiographic scan. It should be noted that the successful passage of a wire or device across a lesion alone without angiographic evidence of adequate restoration of lumen size and elimination of the translesion pressure gradient was not considered an initial technical success, but rather was recorded as being a failed procedure.

### Criteria for continued success

The above criteria for immediate success applied to immediate postprocedural results. Continued success was determined once the patient was discharged and is defined as maintenance of the same criteria listed above for clinical, hemodynamic, and anatomic success. Clinical patency was based on sustained improvement of at least one objective hemodynamic or

imaging test in addition to sustained clinical improvement. A deterioration of one or more category level clinically or hemodynamically constituted failure. Anatomic failure is defined as restenosis to  $\geq 50\%$  of normal diameter as seen on angiographic assessment or doubling of velocities as evidenced by duplex scan. Patients were evaluated at 3-month intervals for the first year and 6-month intervals thereafter.

### Perioperative factors

Endovascular procedures were performed either by percutaneous approach or by arterial cutdown. Typically, a 0.035-inch hydrophilic Glidewire (Meditech, Boston Scientific, Watertown, Mass.) was advanced across the lesion and a 5F introducer sheath was placed. One of a variety of angiocatheters (Meditech) would be selected on the basis of anatomic considerations and advanced over the wire for injection of contrast material and subsequent pressure measurements. Operative imaging was accomplished using C-arm digital subtraction arteriography (OEC Medical Systems, Inc., Salt Lake City). Standard anteroposterior views were routinely augmented with oblique views, and minimal-volume (510 ml) hand injections of contrast material were used to confirm location and severity of occlusive lesions. The pressure measurements above and below the lesion were obtained before intervention. Papaverine injections were used when necessary to evaluate gradients; a 10% reduction in pressure across the lesion was considered significant. Ultrathin angioplasty balloons (Meditech) were selected on the basis of arterial measurements; commonly for an iliac angioplasty a 4 cm  $\times$  8 mm balloon would be positioned and inflated to 12 atmospheres of pressure using an inflation device and the pressure would be sustained for a period of 30 seconds. Patients received a 5000-unit bolus of heparin sulfate intravenously before inflation of the angioplasty balloons.

Premounted Palmaz stents (Johnson & Johnson, Princeton, N.J.) were selected for deployment when angioplasty failed to relieve the translesion pressure gradient or when a technically unsatisfactory result with angioplasty (dissection or residual intraluminal stenosis >30%) was noted. Stent sizes were selected on the basis of arterial measurements and introduced through the 5F sheath when possible. If a 7F introducer was required (necessary for stents larger than 9 mm in diameter), sequential dilators were used to facilitate the exchange. Stent deployment after dilation angioplasty with the next-higher-size balloon catheter was then performed for maximal stent to arterial wall apposition. Completion arteriographic

**Table I.** Patient comorbidities and risk factors

<i>Characteristic</i>	<i>Percent</i>
Hypertension	56
Diabetes mellitus	47
Coronary artery disease	44
Smoking	59
Chronic pulmonary disease	16
Hypercholesterolemia	9
Stroke	8
Creatinine >2.0	2

scans and pressure measurements were obtained in all patients before removal of the introducer sheath. Once removed, if the procedure had been performed from a percutaneous approach, pressure was held for a minimum period of 20 minutes or as necessary to achieve hemostasis.

All patients were discharged on antiplatelet therapy (acetylsalicylic acid, 325 mg daily). Preprocedure and postprocedure thigh-brachial indexes and ankle-brachial indexes were expressed as mean  $\pm$  SD. Apparent differences were assessed for their statistical significance by performing  $\chi^2$  analysis.

## RESULTS

Between October 1993 and March 1996, we performed 109 angioplasty procedures and 41 intraarterial stent deployment procedures in 68 patients who had been referred for evaluation of peripheral vascular disease. The male-to-female distribution was 56% male and 44% female, and the mean age of patients treated was 66.7 years, with a range of 43 to 88 years. Table I summarizes the frequencies of comorbid illnesses and selected risk factors.

Indications for endovascular intervention were disabling claudication in 49%, rest pain in 18%, and tissue loss in 33% of the procedures performed. Table II describes the distribution of lesions and their characteristics.

Of the 60 aortoiliac angioplasty procedures performed (one aortic, 32 common iliac, and 27 external iliac), stents were used in 39 (65%). Of the 32 femoropopliteal artery angioplasty procedures performed, stents were used in two (6%). In no instance was a stent deployed below the level of the popliteal artery to accompany tibial angioplasty. Of the 41 stents deployed, 16 (39%) were used when there was a persistent translesion pressure gradient, and 25 (61%) were used for a poor anatomic result after angioplasty with either residual stenosis >30% (21 procedures) or with angiographic evidence of arterial wall dissection (four procedures). One of the femoral stents was

**Table II.** Description of lesion

<i>Characteristic</i>	<i>No. of lesions</i>	<i>Percent of total</i>
Location		
Aortoiliac	60	55
Femoropopliteal	32	29
Popliteal/tibial	17	16
Type		
Occlusion	6	6
Stenosis	103	94
Length		
$\leq 2$ cm	10	9
2 cm to 5 cm	60	55
5 cm to 10 cm	20	18
>10 cm	19	17
Runoff		
Good (0 to 1 vessel)	47	43
Poor (2 to 3 vessels)	62	57

placed in a patient who had documented blue toe syndrome and a heavily calcified superficial femoral artery lesion refractory to angioplasty; 13 months after the procedure was performed, this patient had resolution of her symptoms and normal distal circulation.

Of the 60 procedures that were performed in the aortoiliac location, five performed in four patients were considered immediate failures. One patient who had a known hypercoagulable condition and severe cardiac and pulmonary comorbidity was being treated for lower extremity ischemia manifested by tissue loss. He underwent percutaneous bilateral common iliac artery angioplasty and stent deployment procedures with a resultant acute aortoiliac thrombotic occlusion. This single case accounted for two of the immediate failures. Application of lytic therapy in an attempt to reestablish patency was ultimately unsuccessful, and the procedure was converted to an axillofemoral and femorofemoral bypass. This patient died on the third day after surgery from disseminated intravascular coagulopathy and acute renal failure and represented the only procedure-related death in the series. The third failed procedure was in a patient who had bilateral lower extremity ischemia manifested by rest pain, who had previously undergone retroperitoneal dissection for creation of an ileal conduit with subsequent pelvic radiation for carcinoma of the bladder. Attempted balloon dilatation and stent deployment resulted in a common iliac artery injury with extravasation of the contrast medium. Balloon control of prograde flow could not be established, and an urgent retroperitoneal dissection with direct repair of the iliac artery injury and creation of a femorofemoral crossover bypass was performed. A fourth common iliac artery dilatation and stent placement occluded during surgery and was con-

**Table III.** Preprocedure and postprocedure pressure ratios

	Preintervention	Postintervention
Aortoiliac procedures		
High thigh-brachial index	0.60 ± 0.13	0.96 ± 0.12
Femoropopliteal procedures		
Ankle-brachial index	0.54 ± 0.14	0.89 ± 0.20
Popliteal/tibial procedures		
Ankle-brachial index	0.46 ± 0.18	0.87 ± 0.22
All procedures		
High thigh-brachial or Ankle-brachial index	0.57 ± 0.15	0.93 ± 0.13

Values are mean ± SD;  $p < 0.05$ .

verted to an aortobifemoral bypass procedure. The fifth immediate failure in the aortoiliac position represented the single instance of failure as a result of an inability to cross the lesion with a wire. This patient underwent a subsequent common iliac–profunda femoris bypass procedure. The resultant initial success rate, defined previously to include the combination of elimination of translesion pressure gradient, improvement in symptomatic status, and successful anatomic result was 55 of 60 cases for the aortoiliac procedures (92%).

There was a significant increase in the high thigh-brachial artery indexes after completion of these procedures. Table III outlines mean systolic pressure ratios measured before and after the procedure for each location separately and for the combined series.

Of the 32 femoropopliteal angioplasty procedures that were attempted, all were for stenotic lesions. There were four immediate failures. In each of these instances the lesions were crossed and angioplasty was performed, but there was no improvement in the pressure gradient. All of these failures were in patients who had critical limb ischemia; two had tissue loss and poor outflow. Neither had a satisfactory bypass alternative and both underwent below-knee amputations, which healed successfully. The other two patients had rest pain and were converted to open surgical procedures at the time of their failed endovascular procedure. The initial success rate for this group was 28 of 32, or 88%. Postprocedure ankle-brachial indexes were significantly improved as compared with preprocedure measurements (Table III).

There were 17 below-knee popliteal and tibial angioplasty procedures performed, all for stenotic lesions. Tibial angioplasty procedures were performed over 0.018 inch small-vessel Glidewires (Meditech) using lower-profile SUB-4 small-vessel balloon dilatation catheters (Meditech). The initial

**Table IV.** Minor and major complications

Complication	Number	Percent
Dissection	4	3.6
Hematoma	2	1.8
Pseudoaneurysm	1	0.9
Cardiac arrhythmia	1	0.9
Arterial wall rupture	1	0.9
Acute arterial occlusion	3	2.7
Acute renal failure	1	0.9

success rate was 16 of 17, or 94%. The one failure was an inability to significantly improve the distal ankle pressure after anterior tibial artery angioplasty. This patient with tissue loss and poor runoff went on to have a below-knee amputation. Overall, the mean postprocedure ankle-brachial index was significantly higher in this group when compared with the mean preprocedure index (Table III).

In the series of 109 endovascular procedures, 16 (15%) were performed as an adjunct to a standard vascular surgical procedure. Eight iliac and two superficial femoral angioplasty procedures were performed as complementary inflow procedures to augment lower extremity revascularizations. Two of these procedures failed when their tibial grafts occluded, and the patients went on to undergo below-knee amputations. This group has a continued success rate of 80% (8 of 10), with a mean follow-up of 10.7 months. An additional external iliac–profunda bypass performed distal to a common iliac angioplasty and stent placement for ischemic rest pain occluded at 6 months. This patient, however, remained symptomatically improved, with an improvement of 0.30 in ankle-brachial index and a patent stent by duplex scan and is therefore considered a continued success.

Six tibial angioplasty procedures were performed in conjunction with femoral-to-above-knee popliteal bypass procedures to augment outflow. One patient had early graft thrombosis with critical limb ischemia, which was treated with successful graft revision. An intraoperative angiographic scan demonstrated continued patency of the previous tibial angioplasty. With this failure the success rate for this group was five of six (83%) with a mean follow-up of 8.6 months. Minor and major complications are summarized in Table IV. The overall complication rate was 11%.

Follow-up has been achieved in all patients, with a range of 2 to 31 months and a mean of 15.7 months. Of the 60 aortoiliac procedures that were performed, five failed immediately, and an additional seven procedures demonstrated deterioration in the follow-up period, for a continued success rate of 80% (48 of 60).

**Table V.** Initial and continued success rates of procedures by length of lesion

Lesion length	Number	Initial success rate	Continued success rate
<5 cm	70	67/70 (96%)	62/70 (82%)
>5 cm	39	32/39 (82%)*	24/39 (62%)*

\*Initial and continued success rates significantly less ( $p < 0.05$ ) for lesions > 5 cm.

Two of these seven procedures were combined with surgical procedures as described above, which failed and required below-knee amputation. One patient had deterioration of his high thigh pressure, return of his rest pain, and outflow stenosis at the site of his previously placed iliac stent. This patient was treated successfully with a second stent placed at the site of the stenosis. The remaining five failed procedures were manifested by worsening of high thigh gradients and symptoms related to restenosis (two cases) and stent occlusion (three cases) and were all treated successfully with femorofemoral crossover grafts.

Of the 32 femoropopliteal procedures performed, four failed immediately, and an additional four procedures demonstrated deterioration during the follow-up period, for a continued success rate of 75% (24 of 32). The four patients whose procedures failed in the follow-up period had deterioration of ankle-brachial indexes, worsening of clinical symptoms, and associated duplex evidence of restenosis at the site of angioplasty. All were treated successfully with femoropopliteal bypass grafts.

In the popliteal/tibial angioplasty group, restenosis developed in two patients who were initially treated for critical limb ischemia that manifested by tissue loss, for a continued success rate of 82% (14 of 17). Both had poor runoff and no reconstructive alternative as a result of restenoses with worsened ischemia and these patients subsequently underwent below-knee amputations.

Fifteen of the 109 procedures were performed after using duplex scanning as the sole preoperative imaging method. Eight of these were iliac artery stenoses, five femoropopliteal stenoses, and two tibial stenoses. Intraoperative angiographic scans were performed to verify the duplex findings, which were universally accurate in this small group. The initial and continuing success rates were 93% (14 of 15), with a mean follow-up period of 13 months.

When initial and continued success rates were evaluated by lesion characteristics, as described in Table II, only the length of the lesion was identified as a significant predictor of failure (Table V). Of the

109 lesions treated, 70 were less than 5 cm in length, and 39 measured greater than 5 cm in length. The initial success rate for lesions less than 5 cm was 67 of 70 (96%), which was significantly greater than success rates for those that measured longer than 5 cm (32 of 39; 82%). This association held true for continued success rates as well, with 62 of 70 lesions (86%) measuring less than 5 cm maintaining a successful result as compared with 24 of 39 lesions (62%) greater than 5 cm remaining successful ( $p < 0.05$ ).

In the current series, the location of the lesion, occlusion versus stenosis, status of runoff, or placement of a stent did not alter success rates significantly. Table VI and Fig. 1 demonstrate life-table analysis for continued success of all lesions treated. Cumulative success rates for all lesions treated were 81% and 72% after 1 and 2 years, respectively.

## DISCUSSION

Performance of therapeutic endovascular procedures has become increasingly common since the first therapeutic use of a vascular catheter by Fogarty et al. in 1963.<sup>3</sup> This initial report of a balloon catheter embolectomy and thrombectomy was followed in 1964 by Dotter and Judkins,<sup>4</sup> who recommended transluminal dilatation of occlusive vascular lesions with coaxial dilating catheters. This initiated a process of evolution that has seen dramatic improvements in technique and the continued development of more sophisticated devices.<sup>5,6</sup>

We have also seen a similar evolutionary process in the valuation of these procedures within the surgical community. Initially accustomed to performing angiographic scans for purposes of diagnosis before performing a surgical reconstruction, most surgeons relinquished these diagnostic responsibilities to colleagues in radiology. The specialty of interventional radiology then developed as an extension to these original diagnostic practices.

As the use of angioplasty techniques expanded, the indications for treatment broadened and new populations of patients were offered therapeutic alternatives that some vascular surgeons have been reluctant to endorse. Concerns were expressed over these newly defined indications and the reported differences in the results between endovascular and standard surgical alternatives. Although the deficiencies of these early methods of reporting have been emphasized,<sup>7,8</sup> as successful reports accumulated indicating that balloon angioplasty could be effective and safe,<sup>9-15</sup> surgeons cautiously began to reexamine their role in the management of patients who have lesions that are amenable to endovascular intervention.

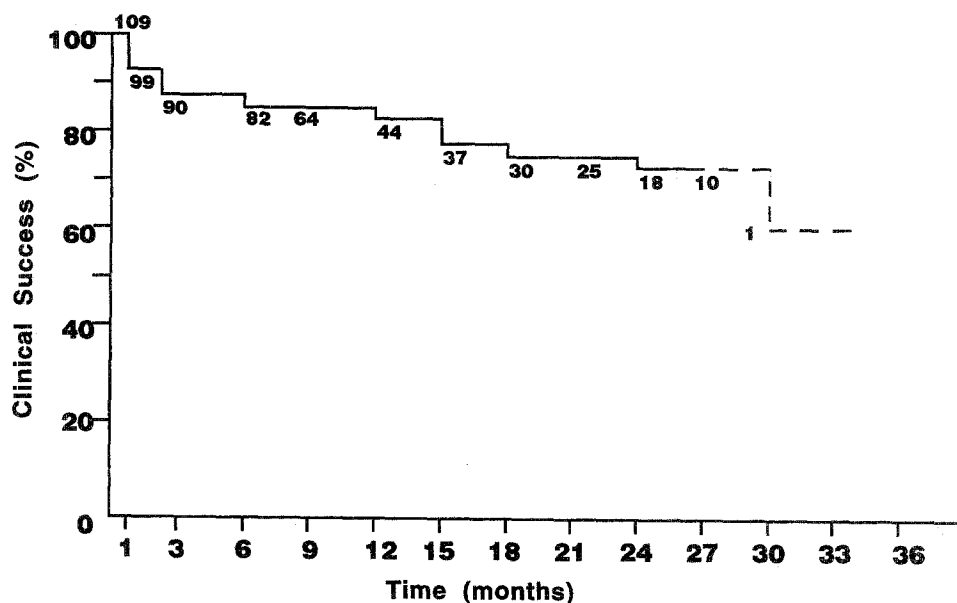


Fig. 1. Life-table plot of cumulative clinical success for all procedures performed.

Table VI. Life-table analysis for all procedures performed

Interval (mo)	No. at risk at start of interval	No. of failures	No. withdrawn patent	Interval patency rate	Cumulative patency (%)	SE (%)
0-1	109	10	0	.91	100	0.0
1-3	99	3	6	.97	91	2.74
3-6	90	2	6	.98	88	3.21
6-9	82	0	18	1.0	86	3.55
9-12	64	3	17	.95	86	3.55
12-15	44	2	5	.95	81	5.32
15-18	37	1	6	.97	77	6.07
18-21	30	0	5	1.0	75	6.85
21-24	25	1	6	.95	75	7.5
24-27	18	0	8	1.0	72	8.98
27-30	10	1	8	.83	72	12.04
30-33	1	0	1	1.0	60	37.9

Some recommended that the surgeon's role should be one of a participant in a team approach directed toward delivering endovascular therapy.<sup>16</sup> The vascular surgeon in this role brings to the group his knowledge of preoperative evaluation and the pathophysiologic mechanisms of vascular disease, the relative risks and benefits of varying therapeutic alternatives, and an expertise with noninvasive means of postprocedure follow-up and assessment of efficacy. In this scenario, typically the actual endovascular treatment is provided by another member of the team, the interventional radiologist or cardiologist, and the vascular surgeon manages the preoperative evaluation and postoperative care and is available for surgical intervention for any complications of the endovascular procedure.

Although initially accepted by many, the limitations of this role have become evident, and vascular surgeons are now participating directly in the performance of endovascular procedures.<sup>17-20</sup> Realizing that evolving endovascular technology may complement or supplant standard surgical alternatives and reluctant to accept a limited role in the management of our patients, many have advocated an expanded role for surgeons in the performance of endovascular procedures and training of vascular surgical fellows.<sup>1,18,20</sup>

Alternative and successful approaches to the development of endovascular training programs have included using cardiac catheterization laboratories<sup>18,20</sup> and the development of freestanding facilities.<sup>21</sup> Neither of these alternatives, however, was

immediately available to us, which resulted in our choice of using the operating suite as the site for the development of a program of operative angioplasty and endovascular intervention.

In our experience, we learned that the C-arm imaging that is available in the operating suite was satisfactory for the performance of aortoiliac, femoropopliteal, and tibial angioplasty procedures. Our success and complication rates are comparable with those reported in other series for procedures that are performed by interventional radiologists who were working alone or with vascular surgeons.<sup>9-15</sup> Similarly, our initial success rate (108 of 109 procedures) in crossing the occlusive lesions with a guidewire has confirmed our bias that surgeons can readily apply their technical knowledge of catheter and wire techniques to a practice of operative angioplasty and stent placement.

It is known that the short-term and long-term results are influenced by the characteristics of the lesion treated.<sup>22,23</sup> In our series, the length of the lesion was a predictor of the clinical success; treated lesions that were shorter than 5 cm had improved initial and continued success rates compared with lesions that were longer than 5 cm. Other factors such as lesion location, status of runoff, and concomitant placement of a stent did not have a significant impact on our early results. We anticipate, however, that long-term follow-up may confirm the significant impact of these variables among the treatment group. It is our goal to continue a program of surveillance for this group, which should contribute some understanding to the significance of these factors in determining the efficacy of endovascular procedures.

The establishment of this program has enabled us to provide our vascular surgical trainees with experience that is sufficient to surpass the recommended minimal guidelines established by the SVS/ISCVS<sup>1</sup> for each of the last 3 years. As new technology becomes available, the ongoing presence of this program should enable us to introduce technical innovations.

Using the experience demonstrated in this series, we recently have attained privileges to use the arteriography suite in one of our affiliate institutions. This is an essential step and has been stimulated by our desire to eliminate the separate preprocedural arteriographic scan. In many of our patients, it is advantageous to proceed with the interventional therapy at the time of the diagnostic arteriographic scan. Another approach, as reflected in 15 of our cases, has been the identification of the occlusive lesion with a preoperative duplex ultrasound scan, thereby elimi-

nating preoperative diagnostic arteriographic scans. This suggests that we can significantly reduce the overall cost of treatment in two ways: by expanding the role of preoperative duplex ultrasound scans, and by performing angiographic scans and therapeutic intervention during the same procedure.

We recommend that vascular surgeons become involved in the selection and performance of endovascular procedures in the operating room as well as in the angiography suite. By establishing an independent interventional program we plan to maintain an active role in the future development of endovascular surgical procedures.

## REFERENCES

1. White RA, Fogarty TJ, Baker WH, Ahn SS, String ST. Endovascular surgery credentialing and training for vascular surgeons. *J Vasc Surg* 1993;17:1095-102.
2. Ahn SS, Rutherford RB, Becker GJ, Comerota AJ, Johnston KW, McClean GK, et al. Reporting standards for lower extremity arterial endovascular procedures. *J Vasc Surg* 1993;17:1103-7.
3. Fogarty TJ, Cranley JJ, Krause RJ. A method of extraction of arterial emboli and thrombi. *Surg Gynecol Obstet* 1963;116:241-4.
4. Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction: description of a new technique and a preliminary report of its application. *Circulation* 1964;30:654-70.
5. Gruntzig A, Kumpe D. Technique of percutaneous transluminal angioplasty with the Gruntzig balloon catheter. *AJR Am J Roentgenol* 1979;132:547-52.
6. Veith FJ, Abbott WM, Yao JST, Goldstone J, White RA, Abel D, et al. Guidelines for development and use of transluminally placed endovascular prosthetic grafts in the arterial system. *J Vasc Surg* 1995;21:670-85.
7. Porter JM. Interventional therapy: an alternative view. *Ann Vasc Surg* 1991;5:101-2.
8. Porter JM. Endovascular arterial intervention: expression of concern. *J Vasc Surg* 1995;21:995-7.
9. Johnston KW, Rae M, Hogg-Johnston SA, et al. Five-year results of a prospective study of percutaneous transluminal angioplasty. *Ann Surg* 1987;206:403-13.
10. Gallino A, Mahler F, Probst P, et al. Percutaneous transluminal angioplasty of the arteries of the lower limbs: a 5-year follow-up. *Circulation* 1984;70:619-23.
11. Veith FJ, Gupta SK, Samson RH, et al. Progress in limb salvage by reconstructive arterial surgery combined with new or improved adjunctive procedures. *Ann Surg* 1981;194:386-99.
12. Bakal CW, Sprayregen S, Scheinbaum K, Cynamon J, Veith FJ. Percutaneous transluminal angioplasty of the infrapopliteal arteries: results in 53 patients. *Am J Radiol* 1990;154:171-4.
13. Palmaz JC, Laborde JC, Rivera FJ, et al. Stenting of the iliac arteries with the Palmaz stent: experience from a multicenter trial. *Cardiovasc Intervent Radiol* 1992;5:291-7.
14. Murphy KD, Encarnacion CE, Le VA, Palmaz JC. Iliac artery stent placement with the Palmaz stent: follow-up study. *J Vasc Interv Radiol* 1995;6:321-9.



15. Johnston KW. Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. *Radiology* 1992;183:767-71.
16. Moore WS. Organization of the multidisciplinary team. In: Ahn SS, Moore WS, editors. *Endovascular surgery*. Philadelphia: W.B. Saunders 1992:12-5.
17. Harris RW, Dulawa LB, Andros G, et al. Percutaneous transluminal angioplasty of the lower extremities by the vascular surgeon. *Ann Vasc Surg* 1991;5:34-53.
18. Hodgson KJ, Mattos MA, Sumner DS. Canine or chameleon: the vascular surgeon's role in percutaneous endovascular therapy. *Vasc Forum* 1993;1:237-47.
19. Schneider PA, Andros G, Harris RW. Balloon angioplasty in the operating room. *Vasc Forum* 1993;4:254-9.
20. Hodgson KJ, Mattos MA, Monsour A, et al. Incorporation of endovascular training into a vascular fellowship program. *Am J Surg* 1995;170:168-73.
21. Diethrich EB. Deficiencies of the modern vascular surgeon: a dilemma, a solution. *Ann Vasc Surg* 1991;5:99-100.
22. Capek P, McLean GK, Berkowitz HD. Femoropopliteal angioplasty: factors influencing long-term success. *Circulation* 1991;83(suppl I):170-80.
23. Johnston KW. Factors that influence the outcome of aortoiliac and femoropopliteal percutaneous transluminal angioplasty. *Surg Clin North Am* 1992;72:843-50.

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## DISCUSSION

**Dr. Frank J. Veith** (Bronx, N.Y.). I certainly applaud Dr. Silva's presentation and generally agree with his conclusions, although I am not sure that duplex scanning can regularly replace pretreatment arteriographic scans. I have one comment and two questions.

The main comment I would like to make is that vascular surgeons must become proficient with C-arm digital fluoroscopy and catheter-guidewire techniques to simplify and improve many of their standard operations. In this regard, at this meeting last year, Drs. Parsons, Marin, and Veith and their colleagues reported on our technique of fluoroscopically assisted thromboembolectomy (*Ann Vasc Surg* 1996; 10:201). Using this technique, the vascular surgeon can navigate tortuous, diseased, clot-filled iliac arteries. Then using a double-lumen balloon catheter passed over a wire, the clot can be removed, stenotic lesions can be corrected by angioplasty and stents, and unsuspected retained clot can be removed. By visually controlling the inflation of the contrast-filled balloon, overinflation and damage to normal or diseased arteries, which is common with standard balloon catheters used without fluoroscopic guidance, can be avoided.

Another example of the use of digital C-arm fluoroscopy and catheter and guidewire techniques to improve or simplify standard operative procedures is the use of double-lumen balloon catheters to obtain proximal and distal control when surgical access is difficult or impossible. This technique is particularly valuable with arteriovenous fistulas and false aneurysms, especially in heavily infected fields. The same techniques can also be used to perform superior intraoperative angiographic scans. Cine techniques with digital fluoroscope provide a dynamic measure of flow through a bypass graft. Moreover, the entire bypass graft plus its inflow and outflow tracts can be visualized and unexpected lesions can be treated without doing extensive open operations.

Thus there are many reasons why vascular surgeons should master the catheter-guidewire techniques and digi-

tal C-arm fluoroscopy mentioned here. The ability to perform balloon angioplasty and stenting is only one such reason.

My first question to the authors relates to their apparently higher-than-usual proportion of patients with claudication in their report today. Do the authors have a lower threshold for performing endovascular interventions than standard operations? In this regard, I think we must be careful to be sure we do not fall into the same trap as some of our interventional colleagues do and treat lesions simply because they are there.

My second question regards how the authors first learned to perform these procedures. Who taught them? We must be sure to get appropriate instruction, help, and consultation in this regard, lest we be subject to the criticism of learning on our patients. I enjoyed this interesting and important paper and appreciate the chance to discuss it.

**Dr. Michael B. Silva, Jr.** Thank you, Dr. Veith. Let me speak first to your suggestion that duplex ultrasonographic scans alone may not be effective in the preoperative diagnosis of all lesions that are potentially treatable by endovascular means. We agree. In this series only 15 of the 109 procedures were performed solely on the basis of duplex criteria. Although we are expanding our use of preoperative duplex scanning to reduce our reliance on traditional angiographic scans, we realize that there are a number of patients with multilevel disease who will require a more detailed preprocedure diagnostic evaluation for which the combination of duplex ultrasound and C-arm fluoroscopy may not be appropriate. To this end, we have obtained credentials to perform angiographic scans in the radiographic suite in one of our affiliate institutions. This may allow us to offer our patients who have more complex disease the opportunity to have both their diagnostic evaluation and therapeutic intervention during a single procedure.

Regarding the number of patients with claudication in our series, a little over one half of these patients were treated for disabling claudication refractory to smoking

cessation, exercise regimens, and lifestyle modification. Although this may represent an expanded role for treatment on the basis of this indication when compared with surgical series of standard surgical therapeutics, we believe that it is appropriate on the basis of the risk-benefit ratio for endovascular procedures. We agree that lesions should not be treated simply because they are there. In this series, all lesions had demonstrable gradients and associated symptoms.

The question of how one learns the techniques involved in the performance of endovascular therapeutics is an important one. The first author of this report underwent a formal 1-year fellowship in diagnostic and therapeutic angiographic endovascular intervention. The second and third authors had substantial experience in the development and evaluation of laser-assisted angioplasty procedures. This experience has been disseminated through the division by a policy of planned proctoring. We believe that the vascular surgeon is ideally suited to perform catheter-based techniques. A number of the procedures that are performed routinely in the conduct of a vascular surgical practice, such as placement of indwelling central venous catheters, placement of Swan-Ganz catheters, placement of arterial lines, placement of vena caval interruption filters, catheter embolectomy, and thrombectomy, lend themselves to the development of skillful catheter-based techniques. Addressing that issue, it should be noted that of the 109 procedures performed, in only one instance was the procedure described as a failure on the basis of an inability to cross the lesion with the wire and the therapeutic device.

**Dr. John J. Ricotta** (Buffalo, N.Y.). One of the big advantages that you can offer to us has to do with what Dr. Veith said before, which is to start to work on algorithms for diagnosis of when to use duplex scans and when to combine duplex with angiographic scans. From a hospital administrator's point of view, this is going to be particularly attractive if you can show that it is cost-effective and avoids two trips to the hospital or two trips to the angiography suite. I think that that's a very important thing for us as a Society, and you and people who are doing this, to concentrate on.

I am a little bit concerned about that common femoral lesion. I am a little concerned that we may be getting so far in bed with the devil that we're going to end up looking like the devil. It's going to be important for us, as we go ahead with this technology, to also define some real indications of when patients are best treated with surgery and when patients are best treated with angioplasty. Again, that's a challenge I think perhaps our Issues Committee, or somebody in this Society, can start to look at. If we start doing everything the radiologists do, we may live to regret it.

**Dr. Silva.** Let me respond first to the issue of how to reduce costs. In our institution we looked at the cost of these procedures on the basis of the site within the hospital where they were performed, and the results were interesting. Operating suite charges are based on the time required for the procedure. Charges in the radiology suite and cardiology suite are based on the procedure itself. As an

example, for an aortogram with lower extremity runoff and iliac artery angioplasty performed in approximately 1½ hours, the charges were actually 5% less when performed in the operating room than those generated by use of the cardiology suite or angiography suite. It is evident that the cost-effectiveness in the operating room can be further improved by reducing the overall time of the procedure itself. To that end we have made such modifications as holding pressure in the recovery room rather than in the operating suite.

To reduce the overall costs to the health care system, we are focusing on two areas. First, by expanding our role of preprocedure duplex ultrasound scanning to evaluate patients who have isolated superficial femoral or external iliac artery stenoses, we can eliminate the cost of the diagnostic arteriogram. Second, by using the angiographic suite for patients who have more complex multilevel disease, we should be able to identify patients who would benefit from therapeutic endovascular intervention during the same procedure.

As to the issue of sleeping with the devil, I agree with you that the techniques we have described do mimic those used in interventional radiology. Of course, surgeons began this process in the 1960s, and many older surgeons recall doing all of their own diagnostic arteriographic scans. I think that to participate in the future of vascular surgery, which will encompass more and more endovascular techniques, we will need to have both procedural skills as well as diagnostic capabilities, and we will have to revisit some of those skills that we readily relinquished to our colleagues in interventional radiology in the past decades.

As for the 20-minute surgical repair of the common femoral lesion, I can assure you that that angioplasty took only 15 minutes and that the patient was doing well at her 1-year follow-up examination.

**Dr. Thomas F. Panetta** (Brooklyn, N.Y.). Clearly, vascular surgeons are both eager and anxious to gain experience in endovascular techniques, and I think you and your group have provided an excellent means with careful forethought, which probably relates to your excellent results. I have three questions, though, relating to this.

First, what is your relationship with your interventional radiologists? Has this been a part of your approach to this? It seems that you're trying to avoid the preoperative angiogram and substitute the duplex evaluation. Along that line, if you're performing the angiographic scan in the operating room, are you getting as complete an angiogram? This may be difficult to do with the C-arm and requires a fair amount of images. Are you doing as complete an angiogram as you should and therefore avoiding proximal and distal injuries that could affect your primary repair?

Again, I also echo Dr. Veith's remarks about not corrupting our principles with regard to treating patients with claudication and liberalizing our indications for these procedures.

**Dr. Silva.** As to the issue of being able to perform a complete aortogram with bilateral lower extremity artery

runoff using the C-arm, we agree that the facilities in our angiography suite are superior to those of our operating room; and as mentioned previously, we are expanding our practice to include the diagnostic arteriographic scans for all of our vascular surgical procedures, which we perform ourselves in the radiology suite.

As to the relationship with our interventional radiologists, as you might imagine, it has become a bit more competitive, but it remains a collegial one nonetheless. We have stressed that this is an important part of our surgical practice as vascular surgeons and that it is a necessary part of our training for our vascular fellows. To learn from one another and foster our mutual development, we have established a combined conference wherein we discuss endo-

vascular procedures performed by the Division of Vascular Surgery and the Department of Radiology.

As to the issue of liberalizing indications, I think that indications will probably be expanded to include patients who have a level of claudication for which we would not offer a more complicated surgical solution, and this has to be based on the risk-benefit ratio of the procedure. If an isolated angioplasty procedure can be performed percutaneously with a local anesthetic on an outpatient basis with acceptable levels of risk and we can demonstrate 1-year to 2-year efficacy rates in the 70% to 80% range, isn't this an acceptable solution for moderate to severe claudication? Our patients think so, and we are inclined to agree.

### LIFELINE FOUNDATION RESEARCH AWARD

The Lifeline Foundation of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery, North American Chapter, invites grant applications for funding of meritorious research by young surgical investigators. The awards are intended for surgeons who have completed their formal surgical education in general surgery and who have completed or are in an advanced training program in vascular surgery.

To be considered for selection a candidate:

1. Should be certified by the American Board of Surgery or have completed the requirements for certification
2. Should submit an application within 5 years of completion of an approved vascular surgery residency training program
3. Must have either a faculty appointment in an approved medical school in the United States or Canada or have received an academic appointment within the guidelines of the applicant's institution

Grant awards are not intended to supplement salary, which will remain the responsibility of the institution in which the awardee holds an appointment. The awardee is expected to devote a significant amount of time to the funded project. A progress report must be presented to the Executive Committee of the Foundation by the following April 1, and, on completion of the project, a brief oral report is to be presented to the memberships of the two societies during a plenary session at the Joint Annual Meeting.

A grant awards committee will review competitive applications. It is anticipated that two grants will be awarded annually totaling \$50,000 each to include indirect costs. The \$50,000 grant includes funding to enable the awardee to attend the Joint Annual Meeting of the Vascular Societies to receive his or her award in the year of selection. Each award will be for 1 year with the option to extend for an additional year.

Holders of substantial research awards, such as an NIH ROI, FIRST Award, or similar support, are ineligible. The applicant must append to the application the abstracts of any funded or pending grants.

Grant applications may be obtained from:

Chairman  
The Lifeline Foundation  
Thirteen Elm St.  
Research and Education Committee  
Manchester, MA 01944  
(508)526-8330

**The deadline for receiving applications in the Foundation office is January 15, 1997. Funds will be awarded by July 1, 1997.**